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| TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i> | Application Number | 10/773,706 |
| | Filing Date | 12/11/2003 |
| | First Named Inventor | James E. Hagstrom, et al. |
| | Group Art Unit | |
| | Examiner Name | |
| Total Number of Pages in This Submission | | 144 |
| | | Attorney Docket Number 48.01 |

| ENCLOSURES <i>(check all that apply)</i> | | |
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| <div style="border: 1px solid black; padding: 5px; min-height: 100px;"> Remarks </div> | | |

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | |
|-------------------------|-------------------|
| Firm or Individual name | Mirus Corporation |
| Signature | |
| Date | 08/02/2004 |

CERTIFICATE OF MAILING

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| Typed or printed name | Mark K. Johnson | | |
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: **James E. Hagstrom,**)
Jon A. Wolff, Vladimir G. Budker,)
Julia Hegge, Hans Herweijer)
)
Serial No.: **10/773,706**)
)
Filed: **12/11/2003**)
)
Group Art Unit: not assigned)

For: A Process Of Delivering A Virally Encapsulated Polynucleotide Or Viral Vector To A Parenchymal Cell Via The Vascular System

INFORMATIONAL STATEMENT

Commissioner of Patents
P.O. BOX 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. 1.56, applicant hereby calls to the attention of the Patent and Trademark Office the publications listed on the attached PTO 1449. This information statement supplements the previously filed information statement.

US patent

6,627,616 issued: 09/20/2003 Mirus Corporation filed: 11/23/1999

REFERENCES CITED

- Acsadi Get al. "Direct gene transfer and expression into rat heart in vivo" The New Biologist; 1991 Vol. 3 no. 1 pp. 71-81
- Budker V et al. "The efficient expression of intravascularly delivered DNA in rat muscle," Gene Therapy; 1998 Vol. 5 no. 2 pp. 272-276
- Chapman G et al. "Gene transfer into coronary arteries of intact animals with a percutaneous balloon catheter," Circ. Res; 1992 Vol. 71 pp. 27-33
- Chowdhury JR et al. "Long-term improvement of hypercholesterolemia after ex vivo gene therapy in LDLR-deficient rabbits," Science; 1991 Vol. 254 pp. 1802-1805
- Ferry N et al. "Retroviral-mediated gene transfer into hepatocytes in vivo," Proc Natl Acad Sci USA; 1991 Vol. 88 pp. 8377-8381
- Greelish JP et al. "Stable restoration of the sarcoglycan complex in dystrophic muscle perfused with histamine and a recombinant adeno-associated viral vector." Nature; 1999 Vol. 5 no. 4 pp. 439-443

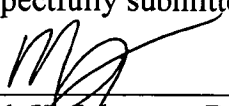
ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.M./

- Grossman M et al. "Successful ex vivo gene therapy directed to liver in a patient with familial hypercholesterolaemia," *Nature Genetics*; 1994 Vol. 6 pp. 335-341
- Hengge UR et al. "Cytokine gene expression in epidermis with biological effects following injection of naked DNA," *Nature Genetics*; 1995 Vol. 10 pp. 161-166
- Hickman MA et al. "Gene expression following direct injection of DNA into liver," *Human Gene Therapy*; 1994 Vol. 5 pp. 1477-1483
- Jaffe HA et al. "Adenovirus-mediated in vivo gene transfer and expression in normal rat liver," *Nat. Genet*; 1992 Vol. 1 pp. 372-378
- Kaleko M et al. "Persistent gene expression after retroviral gene transfer into liver cells in vivo," *Hum Gene Ther*; 1991 Vol. 2 pp. 27-32
- Kaneda Y et al. "Introduction and expression of the human insulin gene in adult rat liver," *J Biol Chem*; 1989 Vol. 264 pp. 12126-12129
- Kaneda Y et al. "Increased expression of DNA cointroduced with nuclear protein in adult rat liver," *Science*; 1989 Vol. 243 pp. 375-378
- Kay MA et al. "Hepatic gene therapy: persistent expression of human alpha 1-antitrypsin in mice after direct gene delivery in vivo," *Hum Gene Ther*; 1992 Vol. 3 pp. 641-647
- Ledley FD et al. "Retroviral gene transfer into primary hepatocytes: implications for genetic therapy of liver-specific functions," *PNAS*; 1987 Vol. 84 pp. 5335-5339
- Li Q et al. "Assessment of recombinant adenoviral vectors for hepatic gene therapy," *Hum. Gene Ther*; 1993 Vol. 4 pp. 403-490
- Liu F et al. "Hydrodynamics-based transfection in animals by systemic administration of plasmid DNA," *Gene Ther*; 1999 Vol. 6 pp. 1258-1266
- Malone RW et al. "Dexamethasone enhancement of gene expression after direct hepatic DNA injection," *J Biol Chem*; 1994 Vol. 269 pp. 29903-29907
- Meyer KB et al. "Intratracheal gene delivery to the mouse airway: characterization of plasmid DNA expression and pharmacokinetics," *Gene Ther*; 1995 Vol. 2 pp. 450-460
- Milas M et al. "Isolated limb perfusion in the sarcoma-bearing rat: a novel preclinical gene delivery system," *Clin Cancer Res*; 1997 Vol. 3 no. 12 Pt. 1, pp. 2197-203
- Riessen et al. "Arterial gene transfer using pure DNA applied directly to a hydrogel-coated angioplasty balloon," *Human Gene Ther*; 1993 Vol. 4 pp. 749-758
- Sikes M et al. "In vivo gene transfer into rabbit thyroid follicular cells by direct DNA injection," *Hum. Gene Ther*; 1994 Vol. 5 p. 837-844
- Soriano P et al. "Targeted and nontargeted liposomes for in vivo transfer to rat liver cells of a plasmid containing the preproinsulin I gene," *PNAS*; 1983 Vol. 80 pp. 7128-7131
- Stratford-Perricaudet LD et al. "Evaluation of the transfer and expression in mice of an enzyme-encoding gene using a human adenovirus vector," *Hum. Gene Ther*; 1990 Vol. 1 pp. 241-256
- Vile RG et al. "In vitro and in vivo targeting of gene expression to melanoma cells," *Cancer Res*; 1993 Vol. 53 pp. 962-967
- Wolff JA et al. "Expression of retrovirally transduced genes in primary cultures of adult rat hepatocytes," *Proc Natl Acad Sci USA*; 1987 Vol. 84 pp. 3344-3348
- Wolff JA et al. "Direct gene transfer into mouse muscle in vivo," *Science*; 1990 Vol. 247 pp. 1465-1468
- Yang Y et al. "Immune responses to viral antigens versus transgene product in the elimination of recombinant adenovirus-infected hepatocytes in vivo," *Gene Therapy*; 1996 Vol. 3 no. 2 pp. 137-144

Zhang G et al. "High Levels of Foreign Gene Expression in Hepatocytes after Tail Vein Injections of Naked Plasmid DNA," Human Gene Therapy; 1999 Vol. 10 pp. 1735-1737
Zhang et al. "Efficient expression of naked dna delivered intraarterially to limb muscles of nonhuman primates," Human Gene Therapy 2001 Vol. 12 no. 4 pp. 427-438

Applicant respectfully requests that these publications be expressly considered during the prosecution of this application and made of record herein and appear among the 'References Cited' on any patent to issue herefrom.

Respectfully submitted,



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I hereby certify that this correspondence is being sent by
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Kirk Ekena

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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT FORM PTO-1449 | Attorney Docket No.: Mirus.048.01 | Serial No.: 10/773,706 |
| | Applicant: James E. Hagstrom, Jon A. Wolff, Vladimir G. Budker, Julia Hegge, Hans Herweijer | Group: |
| | | Examiner: |

U.S. PATENT DOCUMENTS

| Exmnr Intl | Seq | Patent Number | Issue Date | Patentee | Class | Sub Class | Filing Date |
|---------------|-----|---------------|---------------|-------------------|-------|--------------|-------------|
| | | 6,627,616 | 09/20/2003 | Mirus Corporation | 514 | 44 | 11/23/1999 |

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

| | | Document Number | Publication Date | Country or Patent Office | Class | Sub Class | Transl. | |
|--|--|-----------------|---------------------|-----------------------------|-------|--------------|---------|----|
| | | | | | | | yes | no |
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OTHER DOCUMENTS (Including Author, Title, Date Pertinent Pages, etc.)

| | | |
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| | | Acsadi Get al. "Direct gene transfer and expression into rat heart in vivo" The New Biologist; 1991 Vol. 3 no. 1 pp. 71-81 |
| | | Budker V et al. "The efficient expression of intravascularly delivered DNA in rat muscle," Gene Therapy; 1998 Vol. 5 no. 2 pp. 272-276 |
| | | Chapman G et al. "Gene transfer into coronary arteries of intact animals with a percutaneous balloon catheter," Circ. Res; 1992 Vol. 71 pp. 27-33 |
| | | Chowdhury JR et al. "Long-term improvement of hypercholesterolemia after ex vivo gene therapy in LDLR-deficient rabbits," Science; 1991 Vol. 254 pp. 1802-1805 |
| | | Ferry N et al. "Retroviral-mediated gene transfer into hepatocytes in vivo," Proc Natl Acad Sci USA; 1991 Vol. 88 pp. 8377-8381 |
| | | Greelish JP et al. "Stable restoration of the sarcoglycan complex in dystrophic muscle perfused with histamine and a recombinant adeno-associated viral vector." Nature; 1999 Vol. 5 no. 4 pp. 439-443 |
| | | Grossman M et al. "Successful ex vivo gene therapy directed to liver in a patient with familial hypercholesterolaemia," Nature Genetics; 1994 Vol. 6 pp. 335-341 |
| | | Hengge UR et al. "Cytokine gene expression in epidermis with biological effects following injection of naked DNA," Nature Genetics; 1995 Vol. 10 pp. 161-166 |
| | | Hickman MA et al. "Gene expression following direct injection of DNA into liver," Human Gene Therapy; 1994 Vol. 5 pp. 1477-1483 |
| | | Jaffe HA et al. "Adenovirus-mediated in vivo gene transfer and expression in normal rat liver," Nat. Genet; 1992 Vol. 1 pp. 372-378 |
| | | Kaleko M et al. "Persistent gene expression after retroviral gene transfer into liver cells in vivo," Hum Gene Ther; 1991 Vol. 2 pp. 27-32 |
| | | Kaneda Y et al. "Introduction and expression of the human insulin gene in adult rat liver," J Biol Chem; 1989 Vol. 264 pp. 12126-12129 |
| | | Kaneda Y et al. "Increased expression of DNA cointroduced with nuclear protein in adult rat liver," Science; 1989 Vol. 243 pp. 375-378 |
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| | Ledley FD et al. "Retroviral gene transfer into primary hepatocytes: implications for genetic therapy of liver-specific functions," PNAS; 1987 Vol. 84 pp. 5335-5339 |
| | Li Q et al. "Assessment of recombinant adenoviral vectors for hepatic gene therapy," Hum. Gene Ther; 1993 Vol. 4 pp. 403-490 |
| | Liu F et al. "Hydrodynamics-based transfection in animals by systemic administration of plasmid DNA," Gene Ther; 1999 Vol. 6 pp. 1258-1266 |
| | Malone RW et al. "Dexamethasone enhancement of gene expression after direct hepatic DNA injection," J Biol Chem; 1994 Vol. 269 pp. 29903-29907 |
| | Meyer KB et al. "Intratracheal gene delivery to the mouse airway: characterization of plasmid DNA expression and pharmacokinetics," Gene Ther; 1995 Vol. 2 pp. 450-460 |
| | Milas M et al. "Isolated limb perfusion in the sarcoma-bearing rat: a novel preclinical gene delivery system," Clin Cancer Res; 1997 Vol. 3 no. 12 Pt. 1, pp. 2197-203 |
| | Riessen et al. "Arterial gene transfer using pure DNA applied directly to a hydrogel-coated angioplasty balloon," Human Gene Ther; 1993 Vol. 4 pp. 749-758 |
| | Sikes M et al. "In vivo gene transfer into rabbit thyroid follicular cells by direct DNA injection," Hum. Gene Ther; 1994 Vol. 5 p. 837-844 |
| | Soriano P et al. "Targeted and nontargeted liposomes for in vivo transfer to rat liver cells of a plasmid containing the preproinsulin I gene," PNAS; 1983 Vol. 80 pp. 7128-7131 |
| | Stratford-Perricaudet LD et al. "Evaluation of the transfer and expression in mice of an enzyme-encoding gene using a human adenovirus vector," Hum. Gene Ther; 1990 Vol. 1 pp. 241-256 |
| | Vile RG et al. "In vitro and in vivo targeting of gene expression to melanoma cells," Cancer Res; 1993 Vol. 53 pp. 962-967 |
| | Wolff JA et al. "Expression of retrovirally transduced genes in primary cultures of adult rat hepatocytes," Proc Natl Acad Sci USA; 1987 Vol. 84 pp. 3344-3348 |
| | Wolff JA et al. "Direct gene transfer into mouse muscle in vivo," Science; 1990 Vol. 247 pp. 1465-1468 |
| | Yang Y et al. "Immune responses to viral antigens versus transgene product in the elimination of recombinant adenovirus-infected hepatocytes in vivo," Gene Therapy; 1996 Vol. 3 no. 2 pp. 137-144 |
| | Zhang G et al. "High Levels of Foreign Gene Expression in Hepatocytes after Tail Vein Injections of Naked Plasmid DNA," Human Gene Therapy; 1999 Vol. 10 pp. 1735-1737 |
| | Zhang et al. "Efficient expression of naked dna delivered intraarterially to limb muscles of nonhuman primates," Human Gene Therapy 2001 Vol. 12 no. 4 pp. 427-438 |

Examiner:

/Manuel Mendez/

Date Considered:

07/16/2008